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Policies in place throughout the world: action by the European Union

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Introduction

This paper outlines the urgent measures that were under taken from October 2001 onwards by the European Union (EU) following the terrorist attacks in the United States of America (USA). It refers to the EU program of medium and long-term action on chemical, biological and radio-nuclear threats that covers all areas of policy of the EU, including health, agriculture, food safety, internal affairs, financial affairs, civil and environmental protection, transport, energy and research, and analyses in detail the specific program on health security which has been implemented since December 2001 and its results so far.

The health security program constitutes a key component of the EU action on terrorism. It is now being embedded in a wider effort of emergency preparedness and response that became necessary as a result of the lessons learnt from the SARS epidemic. This effort also includes a fundamental review of the agencies and services charged with addressing emergencies and led to the proposal by the European Commission to establish an EU Centre for Disease Prevention and Control, which was adopted by the European Parliament and by the Council of Ministers of the European Union in April 2004.

The EU

The European Union is a union of twenty five Member States – on 1st May 2004, ten countries, namely Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia joined Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and the United Kingdom (UK) to form a single space for more than 450 million inhabitants, in which people, goods, capital and services can circulate freely. Four more countries, namely Bulgaria, Croatia, Romania and Turkey, are candidates for accession.

The EU has firm legal underpinnings that delineate the powers and responsibilities among its central institutions and the Member States. Founding treaties were laid first in the 1950s and revised several times since in inter-governmental conferences. The last opened in the second half of 2003 in Rome and led to agreement on a European Constitution which will have to be ratified by all Member States of the EU in order to come into force.

The EU's law-making entity is the Council of Ministers of its Member States acting, in many areas of policy, together with the European Parliament. The European Commission is the executive branch of the Union and is the sole EU institution that has the power of presenting legislative proposals. Moreover, the Commission can legislate on matters on which it has received delegated authority by the Council and the European Parliament. An independent judiciary

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sits at the Court of Justice and its lower chamber, the Tribunal of First Instance, to adjudicate on matters of violation of European Community law and on interpretation of statutes following applications from national courts.

Looking back

The bioterrorist attacks in the USA in the autumn of 2001 pushed public health emergency preparedness and response to the top of the political agenda. It has been established that a single source was responsible for all the attacks and that the strains of anthrax detected are indistinguishable. This, together with the fact that the perpetrator(s) of the attacks remain unidentified, is a cause of great concern. As long as a proper evaluation is not made public and those responsible for the releases are captured or otherwise neutralised, the risk of recurring deliberate releases of such provenance is considered in the EU to remain high.

The terrorist events took place in the USA but had a worldwide impact. In Europe, civil protection, security and armed forces were put on alert, and public health systems had to manage numerous items of mail containing powders suspected or claimed to be contaminated with anthrax. Until 2003, no terrorist attacks took place in Europe, apart from a contaminated letter found in the USA Embassy in Vienna, Austria, suggesting contamination within USA government postal facilities.

On 7 January 2003, following raids two days earlier in premises in London, the UK authorities announced that a small amount of material found in those premises had tested positive for the presence of ricin, a toxic substance that can be fatal if ingested, inhaled or injected. On 2 June 2003, numerous letters contaminated with adamsite were mailed to various persons and organisations in Belgium and several persons were taken ill. On 20 July 2004, letters containing powder made up mainly of adamsite were sent to various governmental offices in Belgium and, again, several persons were taken ill. All incidents were handled competently but, nevertheless, served as a sharp reminder to security and health authorities to intensify their efforts to plan and be ready for further deliberate dissemination of biological and chemical agents.

Response in the EU following anthrax attacks in the USA

A program on preventive alert for possible emergencies was put forward by the Commission on 28

November 2001¹ that also studied the vulnerabilities of the EU from scientific and technological advances related to bioterrorism. This program was subsequently revised and greatly expanded by the Council and the Commission in December 2002² to cover all chemical, biological and radio-nuclear terrorism with specific reference to the legal and financial instruments in the EU policies for preventing, preparing for, responding timely to and mitigating the consequences of terrorist attacks and threats. The fact that the program was so revised more than a year after the anthrax attacks reflected the continuing preoccupation of EU governments with the terrorist threat. Details of the aforementioned program have been outlined in three reports issued by the European Commission, the first in November 2001,¹ the second in June 2002³ and the third, dealing in detail with health aspects, on 2 June 2003.⁴

Health Sector response

In borderless Europe, pathogens can slip by and spread more easily. Bioterrorism incidents can be hugely disruptive and costly even if they do not kill or maim or involve "unlimited catastrophe" agents, such as smallpox. The Health Ministers of the EU had recognised early the risks from communicable diseases in a borderless Europe and had taken several decisions concerning their surveillance and control prior to 9/11. Following the anthrax attacks, they realised that they had to reckon with a larger challenge. They also had to face up to a spate of hoaxes with packages and letters that were causing fear and panic. At the Council meeting of 15 November 2001, they called for EU action on the following points:

- (a) Development of a mechanism for consultation in the event of a crisis linked to the bio-terrorist risk and a capacity for the deployment of joint investigative teams
- (b) Setting up a mechanism for information on the capacities of European laboratories with respect to the prevention of and fight against bio-terrorism
- (c) Setting up a mechanism for information on the availability of serums, vaccines and antibiotics, including concerted strategies for developing and using those resources
- (d) Setting up a European network of experts in the Member States responsible for evaluating, managing and communicating risks
- (e) Promotion of the development of vaccines, medicines and treatments.

Ottawa Global Health Security initiative

At the same time, on the wider international scene, the bioterrorist attacks were the subject of high-level contacts and meetings. Of particular importance was the meeting in Ottawa on 7 November 2001 of Health Ministers from the G7 group of countries with the participation of the Health Minister of Mexico and Mr Byrne, Member of the Commission responsible for Health and Consumer Protection. The meeting agreed a concerted global action to strengthen the public health response to the threat of international biological, chemical and radio-nuclear terrorism, the outlines of which are given below.

Co-ordination in the European Union

Because of its borderless space and unevenly distributed resources to fight bioterrorism, it is essential that the EU put appropriate arrangements in place to ensure prompt notification and exchange of information in case of threats and attacks, action at source to stem the spread of disease and environmental contamination, mutual assistance for diagnosis and management of cases, access to special laboratory services and expertise for epidemiological investigations, and compatible public health responses. This, in turn, requires sharing of knowledge and good practice, laboratory facilities, equipment and products, and experts and interventional personnel across the Member States of the EU, as well as good co-ordination and interoperability of preparedness and response plans.

The importance of joint action in the EU to complement national measures led to the establishment on 26 October 2001 of a Health Security Committee, comprised of high-level representatives of the Health Ministers, to serve as the main platform for co-operation in countering deliberate releases of biological and chemical agents to cause harm, and to the setting up in 2002 of a Task Force of national experts and Commission officials to implement an action program to enhance health security. The Health Security Committee agreed on 17 December 2001 to a program⁵ of co-operation on preparedness and response to biological and chemical agent attacks (health security), code-named BICHAT, comprising 25 actions grouped under four objectives:

- (a) Set up a mechanism for information exchange, consultation and co-ordination for the handling of health —related issues related to attacks

- (b) Create an EU-wide capability for the timely detection and identification of biological and chemical agents that might be used in attacks and for the rapid and reliable determination and diagnosis of relevant cases
- (c) Create a medicines stock and health services database and a stand-by facility for making medicines and health care specialists available in cases of suspected or unfolding attacks
- (d) Draw up rules and disseminate guidance on facing up to attacks from the health point of view and co-ordinating the EU response and links with third countries and international organisations.

Mechanism of alert and information exchange

This mechanism consists of the Health Security Committee and a rapid alert system (RAS-BICHAT) established to deliver alert notifications and information necessary and appropriate for co-ordinated responses to attacks and threats. The Health Security Committee is charged with exchanging information on health-related threats, sharing information and experience on preparedness and response plans and crisis management strategies, communicating rapidly in case of health-related crises, advising on preparedness and response as well as on co-ordination of emergency planning at EU level, sharing and co-ordinating health-related crisis responses by Member States and the Commission and facilitating and supporting co-ordination and co-operation efforts and initiatives undertaken at EU level.

Rapid Alert System

The dedicated rapid alert system RAS-BICHAT has been in operation since June 2002. The system links the members of the Health Security Committee and also national contact points designated by its members which provide round the clock coverage and urgent recalls in an emergency. The system complements the early warning and response system of the EU for the prevention and control of communicable diseases established in 1998.^{6,7} RAS-BICHAT uses agreed notification procedures and criteria for the classification of events according to the type of release and the severity of consequences, using an incident scale proposed in the context of the Ottawa Global Health Security initiative. It has been used on numerous occasions and is tested continually. Effective links have been established between

that system and other health protection-related EU rapid alert systems, notably on food, animal and plant safety and on emergencies involving radio-activity. The system is also linked to Commission systems that scan and summarise information made available through news agencies, other news media and specialised sources on the World Wide Web. This capability is being extended to involve other sources of information and link up with similar systems operated nationally and internationally, the objective being to facilitate the creation of an integrated “scanning the horizon” information system where data are analysed to rapidly detect, track and assess threats so that advance warning could be provided before official confirmation or news breaks out.

Detection and identification of biological agents

Although any biological or chemical agent capable of causing harm to health may in theory be used for terrorist purposes, a number of considerations, such as ease of production and dissemination, would point to a greater likelihood of some being used than others. It is thus crucial to develop agreed and updateable lists of biological and chemical agents that are considered more likely candidates for attacks, together with their characteristics, associated symptoms and diseases, and indications that permit their timely detection and identification.

Lists in the area of Public Health

Biological agents in relation to bioterrorism have already been prioritised on the basis of certain criteria, such as infectiousness, virulence, persistence in the environment, ease of manipulation and dissemination, and existence of defences to counter their propagation and effects. The European Union has classified biological agents for the purpose of health and safety at work and introduced since 1990 obligations in respect of the possession, storage, handling and use of biological agents in workplaces.⁸ The European Agency for the Evaluation of Medicinal Products (EMA) has referred in the advice⁹ it has given concerning vaccines and treatments to the list published by the Centers for Disease Control and Prevention of the USA that is now linked with the so-called “special agent” provisions in the USA. The Commission has put, since June 2003, under special surveillance *Bacillus anthracis* (for anthrax), *Francisella tularensis*

(for tularemia), *Coxiella burnetii* (for Q fever), and *Variola major* (for smallpox) by their addition to the EU lists of special agents.¹⁰ Moreover, in order to identify and prioritise the different actions needed against biological agents that might be used for deliberate releases in a single tool, a matrix has been developed together with a decision-making algorithm for use by the EU national authorities. The matrix serves to identify, for each agent, the actions that need to be accorded priority and, inversely, the priority agents for each action or counter-measure.

Export control lists

The EU has a compulsory regime¹¹ for the control of exports of dual-use items and technology which contains lists of biological and chemical agents for which strict provisions linked to international non-proliferation regimes and export control arrangements apply. The latter are agreed by international mechanisms, one of them being the so-called Australia Group,¹² an international informal group of countries that base their activities on the biological and chemical weapon conventions regarding the minimisation of the risk of chemical and biological weapons proliferation. The agreements are linked to European Community law. New agents were added to the list in June 2002 but concerns over the adverse impact of controls on public health activities, such as barriers for and delays in the transport of agents, samples, reagents and specimens for tests and comparisons, persist among national public health agencies and laboratories. It is feared that piling up controls without exempting public health agencies from their scope is defeating the purpose of reacting rapidly to threats and stopping outbreaks at source.

- *Laboratories: inventory and co-operation*

Capability for fast and accurate characterisation of biological agents is unevenly distributed in the EU. There are seven laboratory facilities in five Member States of the EU that are suitable for the handling and confirmation in samples and specimens of high-risk agents such as viral hemorrhagic fever or smallpox viruses (P4 laboratories). A network has been formed between these laboratories to provide quality-assured diagnostic services to all Member States, identify viral hemorrhagic fever and pox agents, establish an on-call availability of 24 hours seven days a week, communicate rapidly with national authorities and the Commission, develop a structure for

sending/receiving and handling samples and organise training and skill development.

The Commission is encouraging the conclusion of memoranda of understanding or co-operation agreements between the national laboratory systems of the Member States, such as that existing among the Scandinavian countries; satisfactory progress has already been noted in this area.

Collaboration of high safety level laboratories is also being pursued in the context of the Ottawa Global Health Security initiative.

- *Clinical guidelines for case recognition and management*

Clinical guidelines for the recognition and case management of diseases related to the pathogens that may be used in deliberate releases have been developed on the basis of a consensus process and peer review. Ten manuscripts have been prepared and will be published, on anthrax, smallpox, botulism, plague, tularemia, hemorrhagic fever viruses, brucella, Q fever, encephalitis viruses, glanders and melioidosis.

Chemical agents

Prioritising work has been carried out by the compilation of a series of lists of chemical agents to arrive at groups of substances requiring the same public health and medical approaches. This effort was aided by the co-operation in the context of the Ottawa Global Health Security initiative. It also drew from data on dangerous chemicals collected by the Joint Research Centre of the EU pursuant to European Community law on the control of major accident hazards involving dangerous substances (the Seveso Directive¹³). The risk grading of substances in the agents takes into account the relevant provisions of European Community law on health and safety requirements at the workplace concerning chemical agents.¹⁴

Work is focussing on the clinical and toxicological aspects of chemical incidents, national inventories of chemical experts who can be made available, the inventory of special treatment facilities, clinical review papers on syndromes, and treatment and training issues. Close working relationships have been developed with national and international organisations active in these areas, including the National Focus for Response to Chemical Incidents in the UK, the International Programme on Chemical Safety (IPCS) and the European Association of Poison Control Centers and Clinical Toxicologists (EAPCCT). Data from a survey of poison centres conducted by the Commission have been used to compile an

inventory of clinical and laboratory-related expertise in the EU. Finally, a guidance document on the use of antidotes and pharmaceuticals against chemical agents has been requested and obtained from the EMEA.¹⁵

Emergency plans

Consultations at the EU level and internationally showed that the process of adjusting and complementing emergency plans or devising new ones is not yet complete, with some Member States more advanced than others. Planning is a key priority in the EU and has gained in importance following the SARS epidemic. Member States and other countries are keen to share knowledge and experience and compare assumptions, scenarios, criteria and principles for introducing particular counter-measures at appropriate phases. They want to have flexible and accommodating plans based on carefully considered policy options. These would include the WHO's "search and containment" policy for outbreaks of infectious diseases such as smallpox. Different responses to an outbreak would have to be considered, depending on whether it occurred in one's territory or abroad, as well as responses to multiple outbreaks spread widely, switching between responses, or the scaling up of existing counter-measures. Making measures by the Member States compatible and inter-operable is the key objective. To this end, a compilation of national emergency plans has been made and a general EU plan is being prepared following the SARS experience, which will serve to share and co-ordinate specific measures. An EU-wide exercise will be carried out in 2005 to evaluate communications and compatibility of national plans. Commission participation in the Global Mercury exercise this year, to evaluate smallpox plans and communications involving the parties of the Ottawa Global Health Security initiative, has provided valuable lessons for the conduct of the EU exercise.

Modelling

Member States and the Commission have also embarked on an effort to develop models to make predictions about the progress of disease under different scenarios and variable quantitative and qualitative information on movements of people, social habits, and various geographical, weather and transport and utility conditions. Work on modelling has intensified and is expected to further inform the emergency planning process.

Directories of experts for advice and assistance

Knowledge about bioterror agents and corresponding diseases and their clinical and epidemiological management and associated laboratory analysis is limited. Hence the need to identify relevant experts in the EU and list them in a directory to be shared by the authorities of the Member States. An expert could be made available by one Member State to another on request to the authorities of the expert's Member State. Experts are designated by the Health Security Committee in accordance with criteria on qualifications and experience that have already been drawn up. Other appropriate instruments such as codes of conduct, terms of reference and procedures for the consultation of the directory in strict respect of confidentiality are being developed.

The directory will be managed through collaboration between the Member States and the Commission. It will be co-ordinated with the inventory held by the Commission's civil protection mechanism and the WHO's Global Outbreak Alert and Response Network roster. Regular updates will be made to the contact details of all experts, and new experts will be identified and added at regular intervals.

Availability and stockpiling of medicines

Immediately after the bioterrorist attacks in the USA, attention focussed on the availability of medicines in the EU and the capability of industry and the agencies and laboratories of the 'old' fifteen Member States to make good any shortcomings in production and supply. A consultation with the pharmaceutical industry was launched in November 2001. A joint Commission services-pharmaceutical industry task force was established in December 2001 to address availability, production capability, storage and distribution capacity and development plans for vaccines and other medicines used for the treatment or prevention of disease in the event of a biological attack. In the same month, a specific network was also created via the EU Pharmaceutical Committee, comprising contact points in the aforementioned Member States to look at stocks and availability. At the request of the Commission, the EMEA delivered guidance⁸ on the use of medicines against potential pathogens and a report on second generation smallpox vaccines, based on hearings held with six major vaccine manufacturers, and also gave guidance on the development of vaccinia virus-based vaccines against smallpox.

Antibiotics

Stockpiling of antibiotics has occurred at the national level in many of the 'old' fifteen Member States, but not in all. Some rely on requirements placed on pharmacists, distributors or hospitals but these do not necessarily cover those most suitable for countering bioterrorist attacks. Analysis of the antibiotics capacity of industry showed that there is very likely to be sufficient supply to meet demand in all foreseeable situations. However, it was acknowledged that there might be problems of distribution in an emergency and the aforementioned Member States have since expended efforts to sort out the relevant problems.

Smallpox vaccine

An assessment of national smallpox stockpiles has been carried out which showed that most of the 'old' Member States have or are acquiring stockpiles of smallpox vaccines. First generation vaccines have been in storage since the 1970s. One Member State resumed production of first generation (calf lymph) vaccines in January 2002. Others have ordered second generation vaccines. Some are considering diluting their stock of first generation vaccines to provide a greater number of doses.

From the information received so far, the sizes of the national stockpiles in relation to the national population range from enough to provide a dose for every citizen in the 'old' fifteen Member States to enough for one citizen in thirty. A national stockpile providing total coverage for the population does not necessarily imply a mass vaccination policy – it may reflect a political decision to provide reassurance for the population and to be able to respond to an anticipated public demand. In line with WHO guidelines, all Member States have indicated that they have a targeted vaccination policy. A few Member States have published the key features of their smallpox emergency plans.

A putative EU stockpile

Foreseeable advantages of a EU stockpile of smallpox vaccines were considered to be equity for all EU citizens, increased purchasing power and economies of scale, reduced overall costs up front by having a proportion of stockpile as bulk product and by re-launching production as necessary in response to an emergency, increased leverage to encourage companies to develop new vaccines, industry preference for dealing with one central contact and

boost to confidence from knowing that there is a reserve of vaccine.

However, the issue of sharing and distribution from the stockpile in case of Member States requiring vaccine simultaneously proved difficult. Consultations on options for an EU stockpile or virtual reserve or a strategic sharing of national stockpiles showed that most Member States would not support such options at present. They considered that an EU-level stockpile would not provide added value over the existing and planned national stockpiles, which provide more re-assurance over the key issue of supply in time of need.

Dilution of existing stocks

Studies in the USA showed that under ideal conditions of storage and dilution, up to 5 times dilution would result in doses retaining adequate potency. However, studies launched by the Commission cast doubts on the feasibility of dilution in real conditions.

Second generation vaccines

Second generation vaccines are acknowledged to have superior production and quality control methodology compared with first generation ones but there is uncertainty about their safety profiles as there are no published clinical data as yet. The efficacy of first generation vaccines (in combination with isolation and quarantine) was established during WHO's smallpox eradication campaign, whereas for ethical reasons it will be impossible in present times to establish the efficacy of second or third generation vaccines in clinical trials.

Current situation and actions foreseen

There are no authorised vaccines in the EU against pathogens such as smallpox or plague. The only authorised anthrax vaccine is not widely available. In addition there is an insufficient supply of vaccinia immunoglobulin (VIG), used for the treatment of serious adverse reactions to smallpox vaccine and there is a need for other medicinal products which are currently unavailable or in short supply, such as an anti-botulinum immunoglobulin.

The need to respond in an emergency following a bioterrorist attack could lead to demands for the distribution of non-authorised medicines, which is currently illegal, or to the prescription of off-label or non-authorised medicines, which raises liability

issues. Advantage has been taken of the opportunity presented by the current review of the EU pharmaceutical legislation to introduce legal amendments in order to remedy this anomaly. These amendments are now being examined by the European Parliament and the Council of Ministers of the EU.

For the immediate future, action is being directed towards establishing sufficient quantities of vaccinia immunoglobulin (VIG), and to fostering the creation of a platform for European collaboration to develop and produce biological products such as botulinum antitoxin, an improved vaccine against anthrax and a safe (third generation) vaccine against smallpox. In addition, developments in the production and availability of smallpox vaccines will be reviewed at regular intervals.

Research

The EU has a 12 million euro biosecurity research budget which complements those of its Member States. Its objectives and areas of action have been determined by a high-level peer process. An Expert Group advises the Commission on this issue. Key priorities are rapid diagnostics, detection tools, disease and risk assessment models, new vaccines and novel therapeutics, surveillance methods and periodic appraisal of vulnerabilities.¹⁶

Building a multi-sector response

Chemical, biological, radiological and nuclear terrorism has direct consequences not only for people, but also for the environment, the food chain and for property. Preventing terrorist acts and mitigating their consequences requires a mobilisation of people and resources in many sectors other than health. The joint program adopted by the Council and the Commission on 20 December 2002² reviewed the legislative and other measures already in place and spelled out future actions to improve the multi-sector response that needs to be mounted against a threat or attack in the EU. Of major importance to health security are the measures and actions in food, animal, plant and water safety.

Food safety

The EU has a broad body of legislation, which covers primary production of agricultural products and industrial production of processed food. This legislative body provides different means to respond to situations in specific sectors. The measures that

would be taken in response to a terrorist act in the food sector are not fundamentally different from those adopted by the EU in response to accidents in the recent past. There is no need to establish new systems, but rather to adjust the current mechanisms in order to improve their functioning taking into account the threat of bioterrorism.

The aspect of the fight against bioterrorism that needs developing is the organisation of upstream information, investigation and information-gathering within the territory of the EU and third countries as well as an improved co-operation between authorities and those working in the food chain and their education. Emphasis should also be given to co-operation between the food sector and other sectors of society. In particular, the role of education in guaranteeing safety throughout the food chain must be underlined.

Animal safety

Many EU regulations exist in the area of animal safety. In response to animal health emergencies, the Commission will adopt urgent safeguard measures to supplement existing regulations. The Commission manages a bank of about 40 million doses of various antigens of the food-and-mouth disease virus for the rapid formulation of vaccines. There is on-going reinforcement of banks of vaccines against foot-and-mouth, classical swine fever, avian influenza and bluetongue. Imports are subject to strict controls at the EU borders.

Plant safety

Structures specifically intended to prevent the abuse of plant protection products, which sample, analyse and inspect randomly and at regular intervals, are already in place in the EU. Phytosanitary laboratories exist in all Member States. Strict notification requirements are enforced and inspections are carried out in third countries for plants intended for planting and for specified plant products. A system is also in place for temporary safeguard measures in the case of an imminent danger of introduction or spread of harmful organisms.

Water safety

As regards water safety, EU laws on the quality of drinking water¹⁷ and on the quality of surface waters used for drinking water abstraction are being reviewed to check whether they sufficiently cover

the requirements for constant monitoring of drinking water and other appropriate monitoring and early warning systems. Multi-barrier systems, the use of appropriate markers at key points and the introduction of and adherence to the HACCP system by suppliers are being promoted in the context of the program on health security to enhance safety and confidence in early detection of infective agents and toxicants.

International co-operation

- *Ottawa Global Health Security initiative*

Following the meeting of the G7 group of Health Ministers in Ottawa on 7 November 2001 with the participation of the Health Minister of Mexico and European Commissioner David Byrne, a network of high-level officials was designated for the handling of crises at the international level. A Global Health Security Action Group was also formed to implement the concerted global action plan agreed at Ottawa. The plan foresees the sharing of information and experience on preparedness and response plans, collaboration of laboratories, development of risk communication and management methods, promotion of mutual assistance in means to counter attacks and training for health staff. The Ministers and the Commissioner meet regularly to take stock of progress with the action plan and also share experience with health security developments in their respective jurisdictions.

A communications and plan evaluation exercise code-named "Global Mercury" was conducted in 2003 by the parties to the initiative and the WHO.¹⁸ Under the action plan, an incident scale for risk communication was promoted together with algorithms and guidance for its use. A training course for smallpox trainers has taken place, a network of laboratories was set up and a plan of co-operation on chemical releases was approved. The Global Health Security Action Group is organising a number of workshops to take forward these actions.

- *Co-operation with the WHO*

In addition to the co-operation with the WHO in the framework of the Ottawa Global Health Security Action initiative, the Commission is co-operating bilaterally with WHO on a number of subjects related to countering effects of deliberate release of biological and chemical agents. Important meetings and consultations have been organised by the WHO with direct Commission involvement on key aspects of health sector responses to biological and chemical terrorism.

- **NATO**

A number of meetings have been held between officials from the EU and NATO. An exchange of papers ensued on the respective frameworks, published material and current inventories of activities concerning CBRN incidents and this serves as a basis for further exchange of information and co-operation on deliberate releases. Of particular value in this respect is NATO's guidance and protocols on environmental sampling and assessment concerning such incidents and their update.

Conclusions and perspectives

Since the bioterrorist attacks in the USA, a series of measures have been taken by the Member States, the EU and internationally to reinforce preparedness for and response to deliberate releases of biological and chemical agents to cause harm. The extent and degree of implementation of measures varies between countries, as do their resources in expertise, materials, equipment and facilities.

Of utmost importance in countering bioterrorism is speedy detection of a release and immediate transmission of alert and relevant information to those charged with mounting the appropriate response. Member States are improving their epidemiological surveillance apparatus and their biological and chemical monitoring capabilities and have set up national systems of alert and information transmission. At the EU level, the Rapid Alert System for biological and chemical attacks and threats was set up to allow prompt notification and transmission of alerts and consultation between the Member States and the Commission on counter-measures. The system is expanding to capture and interpret public health intelligence and provide advance warning of outbreaks.

Adequate capacity in public health and health services will be crucial in deciding on counter-measures or switching to different ones. Laboratory capacity is not sufficient in many Member States. The Member States and the Commission are working together to remedy this. Collaboration with the USA, Canada, Japan, Mexico and others on this will be crucial. The EU is also working to assist national health services for emergencies through the issuance of guidelines, the dispatch of expertise and the provision of scientific advice.

Shielding people against agents and mitigating the effects of exposure to them requires recourse to suitable medicines. The European Union's pharmaceutical armamentarium against pathogens and chemicals that can be used in attacks is not yet

complete. Progress has to be made urgently on acquiring vaccinia immunoglobulin, anti-toxins and better and safer vaccines.

The implementation of the European Union's programme on health security helped to drive action on bioterrorism forward. The program is implemented by national experts and Commission officials that work together on health security with the Health Security Committee. The future European Union Centre for Disease Prevention and Control was agreed following a proposal by the Commission in July 2003¹⁸ in the light of the experience acquired following the SARS epidemic which brought home the difficulty of coping with a disease with symptoms like many others and not as distinct (and therefore more easy to identify) as smallpox. This centre will be a key player in providing advice to the Member States and the EU institutions, as well as in implementing surveillance and response actions in the area of health security.

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